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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,810	02/25/2004	Jesus Benavides	ST01023 US CNT	3346

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EXAMINER	
CHONG, YONG SOO	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/786,810	BENAVIDES ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *3-9,11-19,22-28 and 30-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,10,20,21,29,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/24/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's response filed on 12/23/2005. Applicant's election **with** traverse of the restriction requirement in the reply is acknowledged. The traversal is on the ground(s) that there is no search burden because all the claims are found in the same class and that there was no lack of unity of invention imposed in the corresponding PCT application. This is not found persuasive because although the claims are in the same class, the groups are further classified under different subclasses. Restriction practice is different for the US than in PCT applications. Furthermore, the broad claim set presents an undue search burden on the Examiner since a search for one compound or disorder will not lead to information regarding the other. The requirement is still deemed proper and is therefore made FINAL. Claims 1-36 are pending. Claims 3-9, 11-19, 22-28, 30-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-2, 10, 20-21, 29, 35-36 are examined herein.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 10, 20-21, 29, 35-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 11 of U.S. Patent No. 6,355,631 B1 in view of applicant's own disclosure and Durif et al. (US Patent 5,562,917).

In patent 6,355,631 B1 discloses the CB1 antagonist, N-{1-[bis(4-chloro-phenyl)methyl]azetidine-3-yl}-N-(3,5-difluorophenyl)-methylsulfonamide, however does not disclose specifically the combination with levodopa.

Applicant discloses that it is well known that CB1 receptor antagonists have been fully developed for the treatment of Parkinson's disease (pg. 1, lines 23-32).

Durif et al. teach that the classic treatment of Parkinson's disease involves administration of levodopa (col. 1, lines 29-33).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to combine N-{1-[bis(4-chloro-phenyl)methyl]azetidine-3-yl}-N-(3,5-difluorophenyl)-methylsulfonamide and levodopa.

A person of ordinary skill in the art would have been motivated to make this combination because of the therapeutic additive effects for the treatment of Parkinson's disease. See *In re Kerkhoven* below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 10, 20-21, 29, 35-36 are rejected under 35 U.S.C. 103(a) as being obvious over Achard et al. (US Patent 6,355,631 B1) in view of Durif et al. (US Patent 5,562,917).

The instant claims are directed to a combination of a CB1 antagonist azetidine derivative of formula I, specifically N-{1-[bis(4-chloro-phenyl)methyl]azetidine-3-yl}-N-(3,5-difluorophenyl)-methylsulfonamide, and levodopa.

Achard et al. teach a composition comprising azetidine derivatives of formula I, specifically N-{1-[bis(4-chloro-phenyl)methyl]azetidine-3-yl}-N-(3,5-difluorophenyl)-methylsulfonamide (col. 51, lines 22-23) for the treatment of Parkinson's disease (col. 14, line 50). The oral dosage is between 5 to 1000 mg per day with unit dosages

ranging from 1 to 250 mg of active substance (col. 38, lines 20-24). The composition may include diluents and pharmaceutical acceptable solutions (col. 37, lines 32-47).

However, Achard et al. fail to disclose a specific combination with levodopa.

Durif et al. teach that the classic treatment of Parkinson's disease involves administration of levodopa (col. 1, lines 29-33).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to combine N-{1-[bis(4-chloro-phenyl)methyl]azetidine-3-yl}-N-(3,5-difluorophenyl)-methylsulfonamide and levodopa.

A person of ordinary skill in the art would have been motivated to make this combination because of the therapeutic additive effects for the treatment of Parkinson's disease.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SHENGJUN WANG
PRIMARY EXAMINER